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APPLICATION

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Title: **CONTRAST CONTAINER HOLDER AND METHOD TO FILL SYRINGES**

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SPECIFICATION

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CONTRAST CONTAINER HOLDER AND METHOD TO FILL SYRINGES

Field of the Invention

The present invention relates to injectors for injecting fluid into patients.

Background of the Invention

In many medical environments, a medical fluid is injected into a patient during diagnosis or treatment. One example is the injection of contrast media into a patient to improve Optical Imaging, Nuclear Medicine, CT, Angiographic, Magnetic Resonance or Ultrasound imaging, or any diagnostic imaging or therapeutic application using a powered, automatic injector.

Injectors suitable for these and similar applications typically must use a relatively large volume syringe and be capable of producing relatively large flow rates and injection pressures. For this reason, injectors for such applications are typically motorized, and include a large, high mass injector motor and drive train. For ease of use, the motor and drive train are typically housed in an injection head, which is supported by a floor, wall, or ceiling mounted arm.

The injection head is typically mounted on the arm in a pivotal manner, so that the head may be tilted upward (with the syringe tip above the remainder of the syringe) to facilitate filling the syringe with fluid, and downward (with the syringe tip below the remainder of the syringe) for injection. Tilting the head in this manner facilitates removal of air from the syringe during filling, and reduces the likelihood that air will be injected into the subject during the injection process. Nevertheless, the potential for accidentally injecting air into a patient remains a serious safety concern.

In addition to the injection head discussed above, many injectors include a separate console for controlling the injector. The console typically includes programmable circuitry which can be used for automatic, programmed control of the injector, so that the operation of the injector can be made predictable and potentially synchronized with operations of other equipment such as scanners or imaging equipment.

One particular operational routine performed by the injector system is that of filling the syringe with contrast. This filling sequence for a power injector typically requires the use of both hands by the operator. A contrast container is held in one hand in close proximity to the injector while the other hand operates the injector controls to retract the plunger so as to fill the syringe. Even in injectors which can auto-fill a preset volume, the use of both hands by the operator is still required when initially starting the auto-fill sequence.

Accordingly, a need exists to simplify the syringe sequence in power injectors so that an operator can have at least one hand available to perform other activities during the entire operation of filling a syringe.

Occasionally when filling a syringe, the filling sequence can be problematic in that if it is performed too fast, the contrast media is aerated or if it is performed too slow, the sequence can take an unreasonable amount of time to complete. There is, therefore, based on the contrast media and the possible presence of air in the fill tube, a maximum filling rate for contrast media that will avoid aerating the contrast media during filling. While this speed can be programmed in the injector and automatically used, an operator typically monitors the syringe filling to further reduce the likelihood of aeration of the contrast media. A need exists for a filling sequence that permits filling of the syringe with contrast fluid faster than the maximum filling speed attainable if air is present in the fill tube.

Summary of the Invention

Those needs identified above and other problems of conventional injector systems are addressed by embodiments of the present invention that permit hands-free filling of a syringe and by embodiments that perform a filling sequence without aerating the contrast media during filling.

One aspect of the present invention relates to a contrast media injector system that includes an injector head and a contrast container holder connected with the injector head, wherein the contrast container holder is configured to hold a contrast container in a substantially fixed position while the injector head is oriented substantially vertical.

Still a further aspect of the present invention relates to a method for performing a filling sequence in a contrast media injector system having a fill tube coupling a syringe to a contrast media. In accordance with this aspect, substantially all air is expelled from the fill tube and, thereafter, the syringe is filled

at a first rate wherein aeration of the contrast media is prevented and wherein the first rate is faster than a second rate that is a maximum fill rate if air is not previously expelled from the fill tube.

One more aspect of the present invention relates to a method for changing contrast media containers during a syringe filling sequence. In accordance with this aspect, the syringe filling sequence of a syringe is paused when a first contrast container is substantially emptied and the first contrast container is replaced with a second contrast container. Next, substantially all air is expelled from a fill tube coupled between the syringe and the second contrast container and, thereafter, filling of the syringe from the second contrast container is resumed at a first rate wherein aeration of the contrast media is prevented and wherein the first rate is faster than a second rate that is a maximum fill rate if air is not previously expelled from the fill tube.

Brief Description of the Drawings

FIG. 1 illustrates a perspective view of an injector in accordance with principles of the present invention, including a power head, console, and power pack (under a cover), with the syringe, pressure jacket, heater blanket and air detection module removed.

FIG. 2 illustrates a perspective view of the power head of the injector of FIG. 1 with a pressure jacket, syringe and heater blanket mounted thereto, showing the power head display, hand-operated control, and support arm mounting in greater detail.

FIG. 3 illustrates a contrast container holder according to one embodiment of the present invention.

FIG. 4 illustrate a contrast container holder according to another embodiment of the present invention.

FIG. 5 illustrates a contrast container holder according to another embodiment of the present invention.

FIG. 6 illustrates a contrast container holder according to a further embodiment of the present invention.

FIG. 7 illustrates a flowchart of an exemplary method for filling a syringe using an injector system.

Detailed Description of the Invention

MOTORIZED INJECTION SYSTEMS

Referring to FIG. 1, an injector 20 in accordance with the present invention includes various functional components, such as a power head 22, a console 24 and power pack 26 (mounted inside of a cover). A syringe 36 (FIG. 2) is mounted to the injector 20 in the face plate 28 of the power head 22, and the various injector controls are used to fill the syringe with, e.g., contrast media for a CT, Angiographic or other procedure, which media is then injected into a subject under investigation under operator or pre-programmed control.

The injector power head 22 includes a hand-operated movement control lever 29 for use in controlling the movement of the internal drive motor, and a display 30 for indicating to the operator the current status and operating parameters of the injector. The console 24 includes a touch screen display 32 which may be used by the operator to remotely control operation of the injector 20, and may also be used to specify and store programs for automatic injection by the

injector 20, which can later be automatically executed by the injector upon initiation by the operator.

Power head 22 and console 24 connect through cabling (not shown) to the power pack 26. Power pack 26 includes a power supply for the injector, interface circuitry for communicating between the console 24 and power head 22, and further circuitry permitting connection of the injector 20 to remote units such as remote consoles, remote hand or foot control switches, or other original equipment manufacturer (OEM) remote control connections allowing, for example, the operation of injector 20 to be synchronized with the x-ray exposure of an imaging system

Power head 22, console 24 and power pack 26 are mounted to a carriage 34 which includes a support arm 35 for supporting power head 22 for easy positioning of power head 22 in the vicinity of the examination subject. Other installations are also contemplated however; for example, console 24 and power pack 26 may be placed on a table or mounted on an electronics rack in an examination room while power head 22 is supported by a ceiling, floor or wall mounted support arm.

Referring now to FIG. 2, in operation, a syringe 36 and pressure jacket 38 are mounted to power head 22, so that the motor internal to power head 22 may be energized to move a plunger 37 within the barrel of syringe 36 toward and away from a discharge tip 40 of the syringe, to thereby expel fluid from the syringe 36 or fill the syringe with fluid. Pressure jacket 38 provides support to the outer walls of syringe 36 to protect the walls of syringe 36 from failure at high injection pressures.

Syringe 36 and pressure jacket 38 are made of a clear plastic material through which the operator can view the current location of plunger 37 and any fluid or air in the syringe between plunger 37 and discharge tip 40. Accordingly, as described above, an operator may tilt power head 22 upward, fill syringe 36 from a source of fluid while visually monitoring the filling process, then connect the injector to tubing leading to the patient, expel air from the tubing and syringe while visually monitoring the level of fluid in the syringe, and then once air has been expelled, tilt the injector downward and proceed to inject fluid into a subject.

To facilitate this filling process, and other operations that may be performed during injection of a subject, power head 22 includes the hand-operated movement control, which is in the form of the rotatable lever 29. Specifically, lever 29 is rotatable on an axis of rotation inside of power head 22. When the hand-operated control lever 29 is left in its home position, illustrated in FIG. 2, no plunger motion is generated by power head 22. However, when hand-operated control lever 29 is rotated toward syringe 36, forward plunger motion is generated by power head 22, expelling fluid or air from syringe 36. Alternatively, when hand-operated control lever 29 is rotated away from syringe 36, reverse plunger motion is generated by power head 22, filling syringe 36 with fluid or air.

To ensure that fluid injected into a subject is maintained at approximately body temperature, a heater blanket 42 is installed abutting the exterior wall of pressure jacket 38. Heater blanket 42 includes an electrical heater which generates heat for regulating the temperature of fluid within syringe 36. Heater blanket 42 is mounted to a post 44 extending from face plate 28, holding heater blanket 42 in thermal contact with pressure jacket 38.

At the rear end of power head 22 is an indicator lamp 46 (covered by a light-diffusing cover) which indicates the status of the power head.

Further details of exemplary hardware and software which control operation of an injector system such as that illustrated in FIGS. 1 and 2 can be found in U.S. Pat. No. 5,868,710 which is assigned to the assignee of the present invention and incorporated herein by reference, in its entirety.

CONTAINER HOLDER

One particular operational routine typically performed using an injector system is that of filling the syringe 36 with contrast media. This filling sequence for a power injector typically requires the use of both hands by the operator. A contrast container is held in one hand in close proximity to the injector while the other hand operates the injector controls to retract the plunger so as to fill the syringe. Even with injectors which can auto-fill a preset volume, the use of both hands by the operator is still required when initially starting the auto-fill sequence. Accordingly, a need exists to simplify the syringe sequence in power injectors so that an operator can have at least one hand available to perform other activities while filling a syringe.

In particular, one exemplary answer for addressing this need is utilization of a contrast container holder that attaches to a portion of the injector head 22 and secures the container in an orientation conducive to filling the syringe.

The material for this container holder can be any of a variety of suitable materials which are sufficiently rigid to support the weight of a typical contrast container. Preferable materials include plastics, stainless steel, aluminum and certain ceramics. Each of these materials can also withstand sufficient moisture,

chemicals and temperature to easily permit cleaning of the holder by a variety of methods. Additionally, the material of the holder is such that it does not unreasonably contribute to breaking or damaging the contrast container but still functions in an environment in which it will likely receive numerous impacts of various severity.

A particular exemplary design for a contrast container holder is illustrated in FIG. 3; however, one of ordinary skill would appreciate that other functionally equivalent designs are contemplated within the scope of the present invention. The container holder has a receptacle 502, 506 connected with a portion 44 of the injector housing and adapted for holding the contrast container 504 so that a fill tube 510 can easily reach the entire contrast container. More particularly, FIG. 3 illustrates a two piece container holder having an upper, curved arm 502 that curls around the contrast container 504 while a lower arm 506 supports the container 504 from underneath. The two arms 502 and 506 work in conjunction to hold the container 504 titled toward the injector head 22.

The exemplary holder 502, 506 features an open design that facilitates the securing and removing of a contrast container 504 using only one hand. While an operator can, of course, use two hands to insert and remove the container 504, it is not necessary. One hand operation is particularly useful when an operator must replace a container during a filling sequence.

Another feature of the holder 502, 506 is that it positions the container 504 in proximity to the syringe tip 508 so that a fill tube 510 can bridge from the syringe 36 to the bottom of the container 504. Typical fill tubes are 8 inches long but other lengths could be accommodated if desired.

Yet another feature of the contrast container holder 502, 506 is that it tilts the container 504 towards the fill tube 510 when the injector head 22 is appropriately oriented to perform a filling sequence. The previously incorporated U.S. Pat. No. 5,868,710 describes in detail one exemplary system for properly orienting an injector head during filling.

While a range of angles of tilt can be utilized for the holder 502, 506, the container can not be titled so much towards the injector head 22 that contrast fluid leaks out and neither can the tilt be so slight that it prevents the fill tube 510 from reaching the bottom of the container 504. If the fill tube 510 is unable to reach the bottom of the container 504, then the contrast fluid cannot be fully removed from the container 504.

Although FIG. 3 depicts the exemplary container holder 502, 506 attached to the heater jacket 44, the container holder 502, 506 can be coupled with the injector head 22 in a number of ways. For example, the holder can mount or clip on the underside of the injector head housing, or even the faceplate. Also, the holder can attach to the post which holds the heater blanket. In such an instance, the container holder installs on the injector similar to the manner in which the heater blanket attaches. In particular, through a slight interference fit, the holder can snap over a mounting post for convenient installation and permit tool-free removal for cleaning or other operating sequences of the injector that do not require the presence of a container. The holder can also be hinged such that it remains substantially permanently attached to the injector head but can fold out of the way so as to not interfere with other operating sequences or with storing the injector. The attachment of the container holder with the injector should allow tool-

free attaching and removing so as not to further burden the operators with difficult and time-consuming tasks.

FIG. 4 illustrates an alternative embodiment, in which the container 504 is held in a cage 602. The cage is connected to a support arm 604 through hinges 606 (only one hinge is visible in this perspective view). The exemplary hinges 606 can be protrusions that loosely fit into an eye portion of the support arm 604. As the injector is rotated to orient it for filling, the hinges 606 ensure that the container 504 is properly oriented with respect to the injector head 22.

The support arm 604 can be adapted to fit within an opening 610 in the injector or its faceplate. To secure the support arm 604, a locking know 608 can be used that frictionally engages the support arm 604 within the opening 610, when tightened.

FIG. 5 illustrates a clamping alternative for holding the contrast container. According to this embodiment, the holder includes two semi-rigid arms 702 that fit around, for example, the pressure sleeve of the injector head 22. The holder also includes a basket portion 704 that is integrally formed with the arms 702 or otherwise attached thereto. By tightening the knob 706, the arms 702 are flexed inward and securely grip the pressure sleeve during the filling sequence.

FIG. 6 illustrates another type of removable container holder. This holder utilizes a bracket 802 that is affixed to the injector head housing 22. This bracket 802 can also be integrally formed with the housing during its manufacture. The holder includes an arm portion 804 that transitions to a circular opening 808 to hold the contrast container 504. A flange 806 is positioned under the circular opening 808 to prevent the container from falling through. The flange 806 could

be annular or straight (as shown in the figure) and can reach fully across the opening 808 or only reach part of the way.

The above-described embodiments of the container holder illustrate a number of features which one of ordinary skill will readily recognize can be implemented in a number of functionally equivalent ways. Thus, these embodiments are presented as examples and are not intended to limit the present invention to only the specific forms shown.

FILLING SEQUENCE

Occasionally when filling a syringe, the filling sequence can be problematic in that if it is performed too fast, the contrast media is aerated or if it is performed too slow, the sequence can take an unreasonable amount of time to complete. When filling a syringe, operators try to perform the filling at a maximum filling rate for contrast media that will avoid aerating the contrast media. This rate is partly dependent on the contrast media, its viscosity and the possible presence of air in the fill tube. While this speed can be programmed in the injector and automatically used, an operator typically monitors the syringe filling to further reduce the likelihood of aeration of the contrast media. A need exists for a filling sequence that permits filling of the syringe with contrast fluid faster than the maximum filling speed attainable when air is in the fill tube.

One exemplary automatic filling sequence is illustrated as a flowchart in FIG. 7. Of course, a user could perform a manual filling sequence as well without deviating from the scope of the present invention. The first step in an automatic filling sequence, step 902, is to enter a desired fill volume. Once this value is entered, the user can initiate, in step 904, the start of the auto-fill sequence. In

response, the injector system will slowly pull, in step 906, a small volume of contrast into the syringe while the syringe is pointing substantially upwards. An injector head that is oriented so as to have the syringe positioned above the opposite end of the head and to be tilted 45 degrees or less from vertical is considered to be pointing substantially upwards; however, a tilt angle less than 20 degrees is preferable. The small volume of contrast fluid that is pulled into the syringe at a slow enough rate so as not to aerate the fluid is a volume sufficient to be visibly noticed by the operator performing the filling sequence and is usually at least 20 ml.

Once the small volume of contrast is in the syringe, the injector system automatically (or the operator, manually) reverses the direction of the injector ram, in step 908, so that the contrast fluid is expelled from the syringe. In particular, the ram is operated such that at least a portion of the fluid in the syringe travels through the fill tube and re-enters the contrast container. Thus, all air is expelled from the fill tube and syringe.

With no air in the syringe and fill tube, the injector system can energize the ram, in step 910, to pull back the programmed volume with a reduced risk of introducing bubbles due to aeration. The rate at which the contrast media can now be pulled back is faster than if the air had not been previously expelled from the fill tube and syringe as in step 908.

A similar technique can be used to change bottles of contrast media during a filling sequence when the contrast remaining in a container is insufficient to provide the volume of contrast media needed to correctly fill a syringe. This technique is illustrated as steps 912 -920 of the flowchart of FIG. 7. This

technique is useful by itself as a way to change contrast containers during a filling sequence or can be part of an automatic filling sequence as shown in FIG. 7.

During filling, the contrast container may be emptied, in step 912, and air introduced into the fill tube while acquiring the final amount from the container. When the container is empty, the operator can pause the filling sequence, in step 916, using the operator interface of the injector system. As a result of the operator pausing the filling sequence, the ram is stopped so that the empty container can be replaced in step 918 with a new container having contrast media.

The fill sequence can then be restarted in step 920 by the operator. Upon restart, the ram automatically operates in the opposite direction to push air out of the fill tube and syringe. Expulsion of all air from the system, in step 908, is ensured by operating the ram in this direction until contrast fluid from the syringe re-enters the new container. Once all the air is expunged, the ram direction can be reversed to pull up the contrast media, in step 910, so as to fill the syringe. The rate at which the contrast media can now be pulled back is faster than if the air had not been expunged. With the new contrast container available the filling of the syringe can be completed in step 914.

Although the description of the flowchart of FIG. 7 includes the interaction of an operator in many steps, these processes can be automated by appropriate programming of the injector system to perform the steps without requiring the intervention of an operator. In order to program the injector system in this way, assumptions will be made about the volumetric capacity of the fill tube used between the syringe and the contrast container. Knowing this volumetric capacity will allow an automatic routine to draw enough contrast media so that a small amount reaches the syringe and to reverse the ram for a time and speed sufficient

to expel contrast media to ensure all the air is successfully expunged from both the syringe and the fill tube.

Additionally, the routine of FIG. 7 can be automated such that when the operator has replaced the contrast container and instructs the injector system to continue or resume the filling sequence, the injector can control the ram direction and speed to automatically expel sufficient media to ensure the fill tube is cleared of air and then automatically reverse the ram so as to draw more contrast media in at the faster rate.

While the present invention has been illustrated by description of various embodiments and while these embodiments have been described in considerable detail, it is not the intention of the applicant to restrict or in any way limit the scope of the claims to such detail. Additional advantages and modifications will readily appear to those skilled in the art. The invention in its broader aspect is, therefore, not limited to the specific details, representative system, apparatus, and method, and illustrative example shown and described. Accordingly, departures may be made from such details without departing from the spirit or scope of the applicant's general inventive concept.